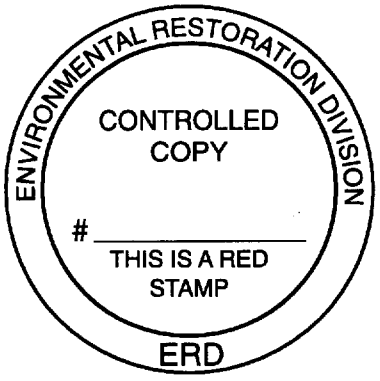
LLNL Environmental Restoration Division (ERD)
Standard Operating Procedure (SOP)

ERD SOP 4.12: Quality Improvement Forms (QIFs)— Revision: 1



AUTHOR(S):
V. Dibley

CONCURRENCES: **Date**

EPD QA Manager — 10/2/00

QA Implementation Coordinator — 9/29/00

APPROVAL: **Date**

Division Leader — 10/4/00

1.0 PURPOSE

The purpose of this procedure is to describe the steps ERD personnel are to take when documenting an identified nonconforming item or process or when suggesting a cost-savings or quality improvement using a Quality Improvement Form (QIF).

2.0 APPLICABILITY

This procedure is applicable to all ERD quality affecting activities.

3.0 REFERENCES

3.1 DOE Order 414.1A, Quality Assurance, U.S. DOE, Washington, D.C.

4.0 DEFINITIONS

See SOP Glossary.

5.0 RESPONSIBILITIES

5.1 The Division Leader

The Division Leader is responsible for fostering a "no fault" attitude to encourage the identification of nonconforming items and processes. The Division Leader is also responsible for allocating resources and resolving difficult quality issues.

5.2 Responsible Manager

The Responsible Manager is responsible for approving the QIF and ensuring the corrective actions/preventative measures are performed.

5.3 ERD Personnel

ERD personnel are responsible for identifying nonconforming items and processes, and suggesting quality improvements. All personnel have the responsibility to stop work until effective corrective action is taken.

5.4 Quality Assurance Implementing Coordinator (QAIC)

The ERD QAIC is responsible for tracking QIFs, ensuring that QIFs contain the necessary information, and verifying that QIFs are satisfactorily closed.

5.5 Responsible Individual

The responsible individual is responsible for completing the corrective action.

6.0 PROCEDURE

6.1 Reasons to Use a QIF

6.1.1. A Quality Improvement Form (QIF) (Attachment A) is used for documenting and resolving identified nonconforming items or processes. A QIF may also be used to document cost savings or quality improvement suggestions. Examples of when to use a QIF:

- Changes to data in the database requiring a paper trail.
- Broken or inadequate material received from vendors.
- Sampling errors.
- Equipment malfunction.
- Treatment facility permit violations.
- Systematic analytical laboratory problems.
- Safety concerns.

- To document the implementation of ISM Function #5, "Provide Feedback for Continuous Improvement."

6.1.2 Questions related to analytical data or suspected errors are documented by the QC Chemists using a Data Review Request (DRR) (see SOP 4.6, "Validation and Verification of Nonradiological Data"). A QIF may be necessary if a change to the database is required or if a trend is identified.

6.1.3 Consult the ERD QAIC for questions regarding the appropriateness of using a QIF.

6.2 Filing a QIF

6.2.1 A QIF may be initiated by any ERD personnel that determines the necessity of a QIF. A QIF should be completed in the following manner:

Step 1. Initiator should obtain a blank QIF from the QAIC. Fill out indicating problem/condition, underlying cause, corrective action taken, responsible individual (if known), as well as preventative measures necessary.

Step 2. Forward completed form to the QAIC.

Step 3. The QAIC will log the QIF into the QIF logbook. Each QIF entry should include a brief summary of the problem, date open, and name of Responsible Manager. The QIF identifier code is assigned (ERD-YY-XXX) by the QAIC, where YY is the current year and XXX is the next available sequential number.

Step 4. The QAIC determines the affected area and forwards QIF to the Responsible Manager.

Step 5. The Responsible Manager reviews the QIF and may make changes or send it back to the initiator if more information is needed. Once the QIF is correct the Responsible Manager fills in the initials box and forwards it to the QAIC.

Step 6. The QAIC will print the QIF and assign a compliance code. The compliance code choices are as follows:

001 = Equipment or system failure.

002 = Defective materials or items.

003 = Calibration deficiency.

004 = Insufficient training.

005 = Procedure noncompliance.

006 = Inadequate procedure.

007 = Documentation deficiency.

008 = Lack of document or record control.

009 = Traceability and chain-of-custody.

100 = Other items not covered above.

Step 7. The QAIC places QIF in the ERD QIF binder.

Step 8. A copy of the QIF is forwarded to the EPD Assurance Manager, Division Leader, Responsible Manager, and all other affected individuals.

Step 9. If the QIF is complete and the corrective action is acceptable, the QAIC will verify the action and close out the form with a signature and a closed date. If the QIF cannot be closed until a corrective action takes place the QIF will remain open until verification.

7.0 QA RECORDS

7.1 Completed QIFs

7.2 QIF logbook

8.0 ATTACHMENT

Attachment A—Quality Improvement Form

Attachment A

Quality Improvement Form

Quality Improvement Form

ERD Personnel should complete Section I and forward the form to the QAIC. The form should be used to document (1) cost savings suggestions, (2) quality improvement, (3) changes to the database, (4) problem resolution, (5) broken or inadequate materials are received from vendors, (6) sampling and analysis error identification and correction, (7) broken equipment/repair, (8) treatment facility permit infractions, (9) other.

Section I

Description of the problem, condition, cost savings suggestion or quality improvement:

Underlying cause:

Corrective action needed or taken:

Preventative measures:

Responsible Individual (person to take action):_____

Section II (To be completed by the Responsible Manager)

Submitted by:_____ **Date:**_____

Responsible Manager Approval:_____

Section III (To be filled out by the QAIC)

QAIC Concurrence:_____

Log Number:_____

Compliance Code: _____

001 - Equipment or system failure
002 - Defective materials or items
003 - Calibration deficiency
004 - Insufficient training
005 - Procedure noncompliance
006 - Inadequate procedure
007 - Documentation deficiency
008 - Lack of document or record control
009 - Traceability and chain of custody
100 - Other items not covered above